

United States District Court  
Western District of New York

United States of America,  
*Plaintiff*

*vs.*

Anthony Galea,  
*Defendant*

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**Defendant Anthony Galea's  
Sentencing Memorandum  
10-Cr-307-RJA**

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Dated: December 9, 2011

Respectfully submitted,  
/s/ Mark J. Mahoney

Brian H. Greenspan, Barrister  
GREENSPAN HUMPHREY LAVINE  
15 Bedford Road  
Toronto, Ontario, Canada M5R 2J7  
Ph: 416-868-1755  
Facs: 416-868-1990  
[bhg@15bedford.com](mailto:bhg@15bedford.com)

Mark J. Mahoney, Esq.  
HARRINGTON & MAHONEY  
70 Niagara Street, 3<sup>rd</sup> Floor  
Buffalo, NY 14202-3407  
Ph: 716-853-3700  
Facs: 716-853-3710  
[mmahoney@harringtonmahoney.com](mailto:mmahoney@harringtonmahoney.com)

(Attorneys for Anthony Galea )

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## **Introduction**

This statement is submitted in order to allow the Court to become more familiar with the defendant, Anthony Galea, and the relevant events, prior to his sentencing. Attached are numerous letters from Anthony's family members and friends. The last section of this memorandum gives an overview of these letters. A review of these letters will confirm for the Court that a sentence for Anthony Galea to any kind of incarceration, except "time served," would be far greater than what would be "necessary" to achieve the legitimate purposes of sentencing.

Efforts by counsel for the defendant, here and in our Statement With Respect to Sentencing Factors, to put the defendant and his conduct in the most favorable light for sentencing fulfills both our obligation to our client and our duty to assist the Court in arriving at a fair sentence. Counsel's demonstration that Dr. Galea might not have been criminally culpable of everything he was originally charged with, however, does not logically or actually detract from his complete acceptance of responsibility and true remorse for what he has pled guilty to – and much more that he has admitted. Counsel's effort, to show that the offense conduct to which Dr. Galea has actually pled guilty is perhaps in the least egregious form in which that offense might occur, is important for the Court to consider in determining sentence. Such advocacy hardly reflects a belief or attitude by counsel, or certainly the defendant, that his offense was not a serious and grave matter. He has acknowledged this and expressed his contrition over and over again, in his plea, in numerous meetings with the government attorney and agents, and does again, now before this Court.

## **Personal Background of Anthony Galea**

Anthony Galea was born in Toronto, on August 19, 1959, to Frances and Joseph Galea. Frances Galea worked in the Cosmetic Industry for Elizabeth Arden. Joseph Galea worked as a bookkeeper for Canadian National Railways.

Dr. Galea has lived in Toronto all his life. He has one sibling, a sister, Janet Curmi. Janet is Vice President of education for Elizabeth Arden and lives in New York City.

Anthony is married to Nela Galea (*nee* Bogdanovich) who was also born in Toronto. He has three children by this marriage, with children ranging in age of 3 to 7, and four by his prior marriage, ages 16 to 23.

## **Children**

His daughter Rachel Galea, 23, following her university studies, started a private tutoring company, “The HiQ Club” in Oakville, Ontario. She specializes in math, science and English.

His son Ryan Galea, 21, will be graduating in finance from McGill University in Montreal this spring. Ryan has been hired by Credit Suisse in New York City and will begin in the summer 2012.

His son Brendan Galea, 18, is also studying finance at McGill University. He is in his first year.

His daughter Madeline Galea, 16, is in grade 11 at Appleby High School in Oakville, Ontario.

His daughter Kaya Galea, 8, is in grade 3 at Fernhill Elementary School in Oakville, Ontario.

His daughter Gabriella Galea, 5, is in Senior Kindergarten at Fernhill Elementary School in Oakville Ontario.

His son Joshua Galea, 3, stays at home with Nela.

Dr. Galea has stated that his greatest achievement is his seven children. He enjoys being a father and has been extremely proud to see his children develop into the beautiful adults they have become. He considers himself to have been blessed to have his wife, Nela, and many close friends. Dr. Galea is an athlete himself and enjoys cycling at a high level with friends – and patients – who are at an elite level in cycling, or just good athletes. When

weather allows he will cycle to his office two days a week, a four hour round trip from his current residence.



## Education

Dr. Galea graduated with honors from the University of Waterloo in 1983. He received a bachelor of science in Health Sciences.

He received his MD from McMaster University Medical School in 1986 and his diploma in Sport Medicine from the Canadian Academy of Sport Medicine in 1989.

## Professional life

### *Employment*

1986-1988            Department of Family Medicine, St. Josephs Health Center, Toronto

1988 -present        Director, Institute of Sport Medicine

1999 – 2001        LifeMark Health Inc., National Director of Sport Medicine. LifeMark had acquired about 20 clinics across Canada and hired Dr. Galea to be in charge of the Sports Medicine Division.

### *Research and Lectures*

Dr. Galea's primary area of interest is Regenerative Medicine and its applications to Sport Medicine. He helped pioneer Platelet Rich Plasma and its applications and is currently using autologous stem cells and their applications in tissue regeneration.

He is currently writing an academic textbook on Human Growth Hormone and has lectured internationally on Platelet Rich Plasma. He recently lectured in South Korea (2011) and at University of British Columbia (2010). He has taught at Hadassah Hospital in the area of PRP in Jerusalem, Israel and, prior to being charged, was conducting research on Protease Enzyme levels and its relationship to PRP injections at the Center of Blood Research at Harvard University.

He has taught international symposiums on drugs and sports; conducted drug testing on behalf of the Center for Ethics in Sports for Canada; lectured on banned substances and methods at the Paralympics; was interviewed by a TV documentary on steroids; and has lectured the Toronto Police Task Force on steroid abuse. [Please see his CV, attached as Ex. A, for further details].

Dr. Galea has done presentations at the Center for Blood research and also at Harvest Technologies, Inc in Boston. He has done in-service training at the offices of colleagues in Pittsburgh and St Louis, Drs. Scarpone and Dr. Crane. During the Atlanta Paralympics he lectured on Doping in Sport.

This past June Dr. Galea was scheduled to be the moderator of a very high level international symposium on PRP therapy, but was pulled entirely from the program due to his arrest.

*Other interests*

In May 2001, Dr. Galea traveled to Jerusalem. He has stated that during that time a series of events had a profound impact on his direction in life. He started sharing his sport medicine expertise and its applications at an Israeli medical center, the Sheba Health Center (SHC). SHC is the largest hospital in the Middle East, with 2,000 in-patient beds.

During this period, Dr. Galea developed a passion in biblical archeology and history, which has led to more than 25 trips to Jerusalem and Israel in the last 10 years. Dr. Galea began to feel as if he needed to do more to help the country and its people. In 2002, he helped finance and set up an advanced Center for Rehabilitation at Tel Aviv's Chaim Sheba Medical Center. Since 2003, he has also been a consultant and researcher at the Orthopedic Rehabilitation Unit at the same hospital. Until his arrest he visited the unit every three months, at his own expense, to teach advanced techniques in rehabilitation.

Since 2008, Dr. Galea has also been teaching at Hadassah Hospital in Jerusalem on the topic of plasma injections. He has been Canada's Chief Medical Officer for two of the International Maccabia Games hosted in Israel.

The following news article puts Dr. Galea's interests in Israel in perspective:

<http://www.cicweb.ca/cannections/galea.cfm>

Sports and Spiritual Healing: A Canadian Doctor's Gift To Israel

Canadian sports doctor Anthony Galea got more than he bargained for when he followed his heart to Jerusalem five years ago. Since then, the illustrious doctor to Toronto Argonaut footballers, Canadian Olympic athletes and American NFL'ers has found his life inexplicably intertwined with Israel. He has devoted his life to bringing Canadian-style sports medicine and practice to the country's best hospitals and is using home-grown Canadian sports medicine practices and technology to heal Israeli soldiers.

By Karin Kloosterman

Galea, raised as a Catholic by Canadian parents of Maltese descent, works specifically with the Sheba Medical Center's Rehabilitation Center, part of Tel Hashomer Hospital just outside Tel Aviv where he has formed the Canadian Friends of Sheba charity . Every three months, "plus or minus a week" he says, since 2001 Galea has been leading a mission to Israel bringing with him influential Canadian and American Christian and Jewish business people to the Holy Land.

They include Toronto businessman Jeff Royer and Toronto Argonaut's owners David Cynamon and Howard Sokolowski.

The Sheba Hospital in Israel runs a rehabilitation centre, the largest of its kind in the region, that features state-of-the-art virtual reality technology for physiotherapy; the hospital's technology, which is some of the best in the world, can be used more optimally, believes Galea, who uses his time and expertise and technology from his private centre in Toronto to help with the recovery of Israeli soldiers and high-profile athletes.

Since Israelis do not play a lot of hockey, baseball or football like Canadians, they can use help with developing sports medicine and exercise physiology practices in other areas, says Galea - a McMaster University Medical School graduate, and University of Toronto faculty member considered one of best sports medicine doctors in the world.

Galea has treated Canadian hockey players such as Gary Roberts, and Canadian track superstars such as Donavan Bailey, Mark McKoy and Perdita Felician.

Choosing Israel as a cause is somewhat of an unusual move for the Catholic boy raised in Etobicoke, Ontario. He plans to make the mix more unusual by speaking Hebrew and currently studies once a week.

One could say Galea's unusual connection to Israel started with a vision. Staying close to his private medical practice in a condo in Toronto's downtown Yorkville neighbourhood, Galea found himself tossing and turning in bed for no apparent reason. Three words circled his head for several nights. They were bringing a message that he couldn't shake.

He heard, "Go to Jerusalem."

It was strange, he admits. As a child, Galea hadn't spent much time in church listening to sermons about the Holy Land nor was he overly familiar with the Christian missions that travelled to Israel for religious pilgrimages.

But Galea had the conviction and rational mind of a scientist and was curious to understand as to what his heart was saying. A week later, he made the mantra of going to Jerusalem a reality and arrived to Israel. It was 2001 and not long after the violence from the second Intifada had erupted. Despite the

warnings, he traveled around Israel ending up at a tear-shaped chapel, Dominus Flevit, at the Mount of Olives in an ancient olive grove. There, he had nothing short of a spiritual epiphany that changed his life forever.

"It felt like someone had put an intravenous in my veins and poured in a combination of fire and love," recalls Galea by telephone from a Mississauga-based clinic where he works once a week.

Although he didn't get any clear answers, the feeling was too extreme to ignore. Soon, he would find himself rehabilitating survivors of deadly terrorist attacks in Israel; and then leading other influential Canadians who had never before visited to come to Israel.

Galea's uncanny draw to Israel and medicine has probably earned him a reputation as one of Canada's most interesting philanthropists. Last year he was featured in the New York philanthropy magazine, *Lifestyles*.

"Why do so many people not want a country to exist? I don't understand," says Galea. "Israel is a very small country. There is no oil. Only desert. The only thing I can figure out that it must be something greater. More divine."

Currently Galea reaches for divinity through his work and is trying to raise money for Sheba's new head trauma department. He would also like to raise money for a mobile rehabilitation unit for soldiers and others in development towns, kibbutzes and other remote locations in Israel.

Now living far from Israel in the Bronte Village neighbourhood of Oakville, Ontario, Galea plans on being in Israel November 22.

"Israel has a great medical system and a good medical infrastructure. It just needs to find ways to use some applications of sports medicine principles with its high-tech - which can be valuable to soldiers and the general public," says Galea whose notable sports medicine achievements in Canada include being the team physician for the Canadian 100 Metre sprint team at the summer Olympics in Sydney, team physician at major Track & Field and Freestyle Skiing Championships since 1989; Galea has also been the team physician at the Toronto Marathon, the Canadian National Figure Skating Championships and Major Tennis Championships (Players International, Du Maurier Women's WTA Canadian Open), and tennis championships such as Players International and Du Maurier Women's WTA Canadian Open.

Galea married a former tennis star from Canada - and she is soon to give birth to their sixth child. It is "kids and families," that Galea sees as most important to both Israel and Canada. "Israelis want the same freedom as Canadians. Like to be able sit with friends and talk over a glass a wine - and you know - all the things we do here in Canada."

And it is hard for him to see the negative press about Israel on television. But there is one aspect about Israelis that keeps Galea drawn to going to Israel

time and time again. "Israelis have a certain tenacity and are free spirits. Everything is there and inside them. They are a touch of Europe, a touch of America and a touch of the East.

While juggling clients on a busy Wednesday morning, Galea repeats the question, "Am I a super-ambassador to Israel? I don't know," he responds. "It is hard to say what drives me. I am not getting paid for what I do and pay for my own hotels and flights. What can I say? I love Israel."

### *Honors*

A sculpture by world famous pop artist [Romero Britto](#) was installed at The Rehabilitation Center at The Sheba Hospital in Israel and dedicated in Dr. Galea's honor at for his contributions in the formation of the center. (see below photos)



## The beginning – a Sports Medicine Practice

Dr. Galea knew he wanted to be a sports medicine doctor with his own clinic even when he was a teenager. His interest stemmed not only from a love of medicine, but a view of Sport Medicine as the ultimate preventative health. Dr. Galea has stated that being able to keep people of all ages and skills exercising for as long possible is the best type of medicine he could provide.

Dr. Galea's drive and focus could be seen even as early as 17, when he approached his neighbor Donna Maltby, a nurse, to tell her of his dream. Dr. Galea asked Donna if she would come to work for him when he opened his own clinic. Thinking he was joking, Donna promised that if he opened his own clinic, she would quit whatever she was doing to come work for him. Years later, after completing his medical training, Dr. Galea called her on her promise and she complied. Donna still works as his office manager.

But before setting up his own clinic, in 1988, Dr. Galea approached St. Joseph's Health Center about opening a large Sport Medicine Facility at the hospital. The hospital was receptive, but eventually required a "needs survey" be conducted. Dr. Galea decided to go out on his own. At the beginning his practice was quite small—he had his manager, one therapist, a receptionist and one other part-time doctor. As time went on and patients continued to receive good outcomes, the clinic expanded.

At that time, there were only a few clinics around the Toronto area. Most of these centers were treating injuries the same traditional way—rest, ice, compression and elevation ("RICE"). However, Dr. Galea's focus was on early detection and intervention to prevent injury.

Leading the way in this was his pioneering use of Diagnostic Ultrasound in sports medicine. Being the first in Toronto and in North America to use the technique gave him an advantage in detecting, locating and monitoring soft tissues injuries. His accuracy in making the correct diagnosis and ability to pinpoint three dimensionally where to intervene with treatment in the recovery effort gave his clinic huge advantage. By the late 1990s, Dr. Galea was recognized widely as an expert.

When Canadian sprinter Donovan Bailey—Olympic Gold medalist and reigning world champion—ruptured his Achilles' tendon, Bailey's prospects of competing in the 2000 summer Olympics were bleak. Defying conventional thought, at the time, Dr. Galea removed Bailey's cast immediately after surgery, and introduced early weight bearing and motion in water. Bailey was able to come back, run under 10 second 100m and compete in the 2000 Olympic games.

During this time, Dr. Galea started using “whole blood” as part of his intervention into specific injuries. He believed that the introduction of blood into the area of injury would speed recovery. This appeared quite successful, however, when reviewing basic physiology, he realized that it was the platelets that were vital in the repair. Among other things, platelets contain “growth factors” which are essential to natural tissue repair. Thus began the birth of “platelet rich plasma” (“PRP”) into his practice. Dr. Galea was probably one of the first in the world to utilize this method of treatment in sport medicine.

As time went on and his abilities to heal injured tissue improved, Dr. Galea was faced with a dilemma. Human Growth Hormone (HGH) was an important, unavoidable hormone in the repair of tissue and present in platelets, and it might be especially effective in some situations on its own rather than as a component of PRP. He understood that one cannot practice reparative medicine without a thorough knowledge of HGH. Dr. Galea began asking lots of questions in light of the demonization of HGH in the sports media and its being banned for use by athletes. Can HGH actually enhance performance? (He does not believe so but if it were to it would have to be several doses throughout the day.) Certainly his use of HGH, in minute quantities at the site of the injury, is not remotely “performance enhancement.” It was therefore perplexing at how HGH—a hormone that is essential in normal body repair has gotten a “bad rap.” Of course the primary problem, which appears starkly in the legislative history, is that HGH had become associated with anabolic steroids, for no good reason, other than it had been found being used often by those using steroids for enhancing muscles and performance.

Those inquiries by Dr. Galea led to the discovery of the “systemic use” of HGH to address adult onset growth hormone deficiency. After measuring his own HGH levels in 1999 and detecting that they were low—which he attributes to a concussion suffered during his youth—in consultation with other physicians and under the care of another physician he started the prescription use of HGH to elevate his own natural levels to the higher end of the normal range. Success in this, and in reviewing success reported elsewhere in similar treatments, has led to substantial incidences of such treatment of his own patients. These treatments – for normal individuals, not professional athletes – are in very small daily dosages far too low to provide any “performance enhancement” and, even despite the

regulation of HGH in the US, had become very widespread in the U.S. long before the arrest in this case.

Today, Dr. Galea's clinic is recognized internationally. He has treated thousands of patients from around the world. Patients come from India, Dubai, Ireland, England, Sweden, Germany, Israel, though the vast majority are from Canada and the U.S.

In managing the clinic's daily affairs, Dr. Galea is the "quarterback" of his team. When a patient presents with an injury, Dr. Galea decides the course of treatment and utilizes different members of his rehab team, or associated practices at the ISM location, to help the patient recover. This includes medical doctors, physiotherapists, massage therapists, nutritionists, exercise physiologists, chiropractors, athletic therapists, podiatrists, nurses, and a uniquely and highly skilled 3-D ultrasound technician. The clinic is not only dedicated to treatment of injuries but also the implementation of therapies to help make sure the injury does not happen again.

## **Focus on Dr. Galea's Expertise**

Dr. Galea's expertise today builds on this past. He is still a pioneer in the use of 3-D ultrasound for diagnostic purposes and for insuring that his interarticular (joint) and intramuscular injections are introduced at the precise points where the injury is located. He specializes in "minimally invasive musculoskeletal" therapies, which include the use autologous substances in PRP, the patient's own stem cells, and homeopathic medicines such as HGH, Actovegin®, Traumeel® and Zeel®.

As noted above, Dr. Galea was trained at McMaster University in Hamilton Ontario Canada. It is important to note that this medical school is a pioneer of self-directed learning and regarded as the birth place in the 1980's of what, in the study of medicine, is called "Critical Appraisal."<sup>1</sup> Critical appraisal is the process of carefully and systematically examining research to judge its trustworthiness, and its value and relevance in a particular

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<sup>1</sup> See, Allan D. Kitching, Gordon H. Guyatt, "The Critical Appraisal Club," CMAJ, VOL. 136, APRIL 15, 1987 describing the origins of the Critical Appraisal program at McMaster. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1492093/pdf/cmaj00140-0037.pdf>

context. It is an essential skill for what is called “evidence-based medicine” because it allows clinicians to find and use research evidence reliably and efficiently.

Accordingly, Dr. Galea was taught, and trained to recognize that if he lacked the knowledge needed to solve a problem at hand, he did possess the skills to find whether anywhere in the medical world there were the solutions to the problems he was trying to solve, and to evaluate that research to determine whether it was probably useful to the treatment of the patients he was dealing with.

One problem he confronted in the late 90’s was, “how do you control inflammation in the joints, without the destructive effects of what we had available at the time,” *i.e.* the “cortisone” family of drugs. While these drugs relieve symptoms, they damage cartilage making future injuries more likely and repair more difficult. This is when he discovered several protocols patented by Florida physician Allan Dunn, using human growth hormone in the treatment of injuries and inflammation. Dr. Galea changed Dr. Dunn’s protocols because Dunn used an anesthetic called Marcaine within his protocol which had its own destructive properties on cartilage. This inquiry also led him to the discovery of Actovegin® and its regenerative abilities and finally to whole blood, platelets and eventually the use of the patient’s own stem cells.

**We must note here that, despite it's importance in this discussion, the use of HGH is involved in less than 1% of Dr. Galea's patients.**

## **Autologous Substances**

Dr. Galea treats patients using their own blood, after separation into a Platelet Rich Plasma (PRP) fraction. Although Dr. Galea was a pioneer in the use of “Platelet rich therapy” (“PRP”) in North America, and the use of HGH in minute amounts in the curing of tissue injuries, he was not alone. He was aware of other physicians in the U.S. who were using these techniques, including HGH, in the same way. Principal among them was Dr. Dunn, who actively advertises the availability of this mode of treatment.<sup>2</sup> This has been reported , for example in Sports Illustrated, noting specifically that Dr. Dunn’s practice had

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<sup>2</sup> See <http://www.iagh.com> Dr. Dunn’s Patent is also attached as an exhibit, Ex. B.

not been interfered with by the FDA notwithstanding. “Hormone Imbalance - Canada and the U.S. are worlds apart on HGH laws,” David Epstein, September 27, 2010, Sports Illustrated:

It is unlikely that any Florida agency would take issue with Dunn’s prescribing of HGH, but federal agents who monitor HGH issues could pay him a visit if they were so inclined.

Sr. Galea’s belief that HGH treatment was acceptable in the U.S. finds support in the number of doctors notoriously using these techniques and advertising the fact in the U.S. Attached is a compendium of Web pages for doctors using HGH in interarticular (joint) treatments and for other purposes not specifically approved by the FDA. Ex. C.

Indeed, in another area, “anti-aging,” HGH is also widely used in the U.S., despite the FDA understanding of the statute. The JAMA article “Provision or Distribution of Growth Hormone for “Antiaging” - Clinical and Legal Issues, Thomas H. Perls, MD, MPH, Neal R. Reisman, MD, JD, S. Jay Olshansky, PhD, October 26, 2005—Vol 294, No. 16, it is observed at the outset:

The Distribution and Marketing of Human Growth hormone (HGH or GH) via Web sites and antiaging clinics has grown into a multimillion-dollar antiaging industry. (*footnotes omitted*) Despite congressional hearings warning of deceptive marketing claims and the potential health and economic dangers associated with the antiaging industry, (*footnotes omitted*) and statements issued by the National Institute on Aging and the Federal Trade Commission, (*footnotes omitted*) the distribution and use of GH for antiaging is now common. For example, entering the terms “HGH” and “anti-aging” into the Google search engine generated 3,410,000 hits as of September 26, 2005, many representing Web sites and clinics marketing and selling GH.

#### *Anomalous case of HGH and “off-label” use*

What is not well known, and what was not known to Dr. Galea, and apparently these numerous U.S. physicians, was that, as a result of an historical regulatory accident, HGH has become the only pharmaceutical nominally unavailable for “off-label” use. The government,

in its response to our Statement With Respect to Sentencing Factors, seriously misunderstands our point on this, as we shall demonstrate.

Ordinarily, a physician can prescribe any drug, including a controlled substance, for a purpose for which it is not specifically approved, as long as there is a “legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR § 1306.04(a).<sup>3</sup> This is called “off-label” use. HGH is not a controlled substance. It is *approved* for some uses. Ordinarily, despite being approved for a limited number of uses, any physician could have lawfully prescribed in accordance with § 1306.04(a). However, HGH had previously been associated anecdotally, and then in the regulatory scheme, with anabolic steroids as a means for muscle and performance enhancement for body builders and athletes. Legislation in the 1980's and 1990's left it in a peculiar and truly anomalous position.

### **The 1988 Amendments<sup>4</sup>**

In recognition of the fact that abuse of anabolic steroids was becoming larger in scope and presenting an ever-increasing health risk to young athletes, Congress enacted as part of the 1988 Anti-Drug Abuse Amendments, Pub.L. No. 100-690, §§ 2401, 2403 (effective

<sup>3</sup> 21 CFR §1306.04 - Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for “detoxification treatment” or “maintenance treatment,” unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in §1301.28 of this chapter.

<sup>4</sup> Most of the statutory history here is extracted directly from the U.S. Attorney’s Manual, Civil Resources Manual, Title 4, Civil Resource Manual, Ch. 19.

November 18, 1988) prohibitions on distribution of steroids. This created a new statute, 21 USC § 333(e)(1), which made the distribution of anabolic steroids illegal unless (1) it was done pursuant to the order of a physician, and (2) it was for the purpose of treating a disease. Obviously at this time Congress had no clue that there would be a range of medical uses for HGH that had not been presented yet, and uses that in no way implicated the concerns that had associated HGH with anabolic steroids.

### **The 1990 Amendments**

In 1990, Congress enacted more stringent controls with higher criminal penalties for distributing anabolic steroids. The focus on steroids is in the title: “Anabolic Steroids Control Act,” Pub.L. No. 101-647, Title XIX, §§ 1901-05. The 1990 Act reclassified anabolic steroids as Schedule III controlled substances, effective February 27, 1991. See 21 U.S.C. § 812(c) (1992). The 1990 Act also added a provision amending 21 U.S.C. § 333(e)(1) to explicitly criminalize as a five-year felony the distribution and possession, with intent to distribute, of human growth hormone “for any use . . . other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Human Services . . . and pursuant to the order of a physician . . .” This residual phrase “authorized by the Secretary of Human Services,” is a restriction which does not apply to other drugs, including controlled substances (which growth hormone is not). The choice not to maintain a 1:1 association between steroids and HGH recognized that the two substances actually have completely different characters, with many recognized medical uses for HGH which is also produced naturally in the human body.

But the quirky regulatory history left this anomalous restriction on prescriptions for HGH when it was substituted for anabolic steroids in this new statute. Nothing in the Congressional history of the HGH statute suggests that Congress ever intended to restrict the prescription of HGH, more than that of steroids and all other Schedule II through V controlled substances. The unintended result is that HGH became the most highly restricted prescription drug. This situation certainly does not reflect any heightened dangerousness in the drug, but rather, a historical legislative anomaly.

Because Dr. Galea saw U.S. physicians getting patents for the use of HGH in tissue repair, and because he saw them actually using HGH in such treatments, and because he had

concluded (correctly) from Web marketing that HGH had been approved for use, he had no understanding that its medical use in the U.S. was any less permissive than it was in Canada.

This is how it was put by Sports Illustrated writer David Epstein, probably the most knowledgeable writer on the topic:

In an apparent effort to regulate HGH less tightly than steroids, Congress swapped HGH into the trafficking law from which steroids had been removed. But the wording of the regulations got ambiguous. Today, the law effectively limits distribution of HGH to adults to three specific FDA-approved treatments: for AIDS-related wasting, short bowel syndrome and growth hormone deficiency. The law has been interpreted to bar off-label prescribing of HGH, whether or not that was the original intent (and, some doctors argue, regardless of whether potential off-label applications show therapeutic promise).

Interpreting the law has been confusing for many American doctors, and apparently for Galea as well. At a March talk in Vancouver, Galea said off-label use of HGH is allowed in the U.S. and cited Florida orthopedic surgeon Allan Dunn as a pioneer of it. Dunn has treated approximately 1,000 patients with HGH, including athletes; former NFL running back Abdul-Karim al-Jabbar was a patient. Dunn says he found that injecting growth hormone into the joints of mature rabbits regenerated cartilage, and that HGH injected into knees helps the human body to grow cartilage. “This has saved a number of my patients from needing a total knee replacement,” says Dunn, adding that off-label use of HGH is “perfectly legal in many states.” (Research indicates that many states simply don’t have an explicit law regarding off-label use.)

“Hormone Imbalance - Canada and the U.S. are worlds apart on HGH laws,” David Epstein, September 27, 2010, Sports Illustrated. Thus, based on the above, it simply cannot be denied that the rule prohibiting “off-label” use of HGH is anomalous, and that, as a result, many doctors are not aware of it.

The use of PRP has grown exponentially in the last several years. At a recent North American PRP symposium, Dr. Lewis Maharam, the past president of the New York chapter

of the American College of Sports Medicine, stated that he believes “PRP is the greatest advance in sports medicine since the MRI (magnetic resonance imaging).”<sup>5</sup>

Just two years ago, at the time Dr. Galea was charged, the use of PRP, was done by relatively few practitioners. It seems to be very much the case that the charges against Dr. Galea have a lot to do with the significant rise in the use of PRP. Indeed, at the time that Harvest Technologies, the company making the most popular PRP centrifuge, and “kits” for the procedure, called Dr. Galea to inform him that they were removing him as the moderator of the North American PRP program in Toronto, mentioned above at p. 8, they also acknowledged that they had benefitted from the publicity he provided to their product. Their sales had increased and PRP units and kits were being sold world wide.

Thus, one has to step back and take a broader view to put into perspective the failure of this particular Canadian doctor – in the company of so many U.S. doctors – to appreciate or be aware of the FDA position prohibiting HGH use for valid medical purposes for which, for whatever reason, there had not been specific approval.<sup>6</sup>

The government maintains that it is irrelevant that “off label” prescription of HGH is permitted in Canada, and that doctors here in the U.S. were either oblivious to or defiant of the regulations “because such comparisons do nothing to prove whether such uses are lawful.” [Dkt#24, p. 6-7] Plainly, it is not our suggestion that “such uses are lawful.” Far

<sup>5</sup> [http://articles.nydailynews.com/2011-05-22/sports/29588585\\_1\\_colon-procedure-cell-treatment-joseph-purita](http://articles.nydailynews.com/2011-05-22/sports/29588585_1_colon-procedure-cell-treatment-joseph-purita) Two years earlier this same doctor had actively participated in a slanderous media lambasting of Dr. Galea, and open – and completely baseless and unfair – innuendo concerning Tiger Woods’ having consulted Dr. Galea, falsely calling Dr. Galea a physician “who specializes in performance-enhancing drugs” with a typical Daily News headline wildly referring to a “steroid-tainted doc.” [http://articles.nydailynews.com/2010-02-19/sports/27056789\\_1\\_tiger-woods-answer-questions-drugs](http://articles.nydailynews.com/2010-02-19/sports/27056789_1_tiger-woods-answer-questions-drugs) Such is the ignominy that Dr. Galea has had to unfairly suffer as a result of his conduct resulting in his arrest.

<sup>6</sup> The fact is, however, that the HGH actually in the possession of Ms. Mary Anne Catalano at the border at her arrest was for personal use by Dr. Galea pursuant to his lawful prescription in Canada to address clinically low HGH in his system. It was not for any patient in the U.S. Dr. Galea has many patients (who are fully screened for the purpose and meet strict clinical criteria) who are similarly on maintenance treatments with very small dosages of HGH. We have pharmacy records of the dispensation of the HGH to Dr. Galea pursuant to prescription. Of course this does not dispute that, on several other occasions Dr. Galea imported HGH for use in medical treatment of patient injuries, which he has completely admitted and forthrightly discussed in every detail.

from it. Our obvious point is that, to the extent that the Court considers it at all, since it is not strictly part of the instant offense, Dr. Galea's use of HGH on patients here in the U.S., though improper for several reasons, was not *knowingly* in violation of the 21 USC § 333(e) preclusion of "off label" use. This is an important mitigating factor we could not fail to bring up.

## **Stem Cells**

The patient's own stem cells can be harvested from patients' bone marrow or fat and used to treat areas of injury. Thus this is not an ethically problematic area like the use of embryonic cells.

Fat stem cells can be combined with PRP; stem cells taken from bone marrow already contain platelets. Stem cells are stimulated by growth factors to change them into the type of tissues in need of repair after they are injected into that tissue. Interest in these stem cell treatments has continued.<sup>7</sup>

## **Additional Therapies**

Dr. Galea also used Actovegin®, Traumeel® and Zeel®

### *Actovegin*

Actovegin is manufactured by Nycomed, reportedly one of the world's 25 largest pharmaceutical companies until it was acquired in 2011 by Takeda, a Japanese company, which now, combined, ranks 12th in global prescription sales.<sup>8</sup> Actovegin is described by the company as follows:

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<sup>7</sup> "Peyton Manning's receiving stem cell therapy thrusts medical procedures back into sports spotlight," Daily News, September 18, 2011.

[http://www.nydailynews.com/sports/iteam/2011/09/18/2011-09-18\\_peyton\\_mannings\\_receiving\\_stem\\_cell\\_therapy\\_thrusts\\_medical\\_procedures\\_back\\_into.html#ixzz1YQWKcbRJ](http://www.nydailynews.com/sports/iteam/2011/09/18/2011-09-18_peyton_mannings_receiving_stem_cell_therapy_thrusts_medical_procedures_back_into.html#ixzz1YQWKcbRJ)

<sup>8</sup> <http://www.nycomed.com/about-nycomed/>

Product description: Actovegin® is a protein-free prescription product obtained from calf blood. Actovegin® has been in clinical use for over 40 years. Actovegin® is prescribed by hospital specialists and general practitioners in selected European markets, Russia and the CIS, China and South Korea. Actovegin® is available as tablets, injections and infusions. Over-the-counter (OTC) formulations (cream, gel, ointment) are also available.

Medical need: Actovegin® is used in indications that include disturbances in cerebral circulation (e.g. cranio-cerebral traumas), peripheral blood flow (e.g. arterial angiopathy), skin graftings, burns, scalds, abrasions, wound-healing impairment, and radiation-induced skin and mucous membrane lesions (prophylaxis and therapy).

There are no evident web reports of any safety or health issues arising from the use of this medicine. An article in the Current Sports Medicine Reports of the American College of Sports Medicine recites that “Although the active ingredients in Actovegin are yet to be identified, many clinical studies have indicated its safety and effectiveness.”<sup>9</sup>

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<sup>9</sup> Paul Lee, MBBch, MRCS, MFSEM, PgDip(SEM); Alvin Kwan, BSc, PhD; and Len Nokes, BEng, MSc, PhD, MBBCh, MD, PgDip(SEM), FFSEM, FIMech, “Actovegin – Cutting-edge Sports Medicine or “Voodoo” Remedy?” Current Sports Medicine Reports. Vol. 10. No. 4 & July/August 2011 (American College of Sports Medicine). This article does not report on any new research of the authors. Rather it surveys the literature on Actovegin. It provides a more detailed description of Actovegin:

ActoveginA is a deproteinized hemodialysate of ultrafiltered calf serum from animals under 8 months of age, produced by Nycomed GmbH, Linz, Austria. Austria is officially categorized as a bovine spongiform encephalopathy-, transmissible spongiform encephalopathy-, and scrapie-free country by the World Organization for Animal Health and the Scientific Steering Committee of the European Union. The manufacturing process of ActoveginA is bovine spongiform encephalopathy validated, thus proven to be capable of removing hypothetically present transmissible spongiform encephalopathy agents (23). It is ultrafiltered to 6,000 Da; therefore, it does not contain protein, growth factors, or hormonelike substances. ActoveginA contains physiological components, electrolytes, and essential trace elements. Amino acids, nucleosides, and intermediary products of carbohydrate and fat metabolites constitute approximately 30% of organic components in ActoveginA (23). The active ingredients in this mixture have yet to be identified.

The article concludes that there is no evidence of Actovegin being used successfully for “performance enhancement” but that it is potentially useful for the treatment of tissue injuries (as Dr. Galea has used it).

When Dr. Galea researched the availability of Actovegin for use in his treatments, it was a drug widely used in Europe and other countries. It has been in clinical use for 60 years. It can be ordered and delivered by mail in Canada, and was marketed as “FDA approved” from internet sources accessed by Dr. Galea. It is also not listed as a banned substance by any of the anti-doping bodies (nor does it have “performance enhancement” characteristics).

The government misunderstands our reason for observing that Actovegin, though not *approved for use* by the FDA has not been *disapproved*. Our point is that it would be wrong to think that it is not approved because it was found to be unsafe or ineffective. The drug product’s manufacturer, Nycomed Austria GmbH, has *never sought FDA* approval to market the drug by submitting a New Drug Application (“NDA”). In a news story prompted by this case, Karen Riley, a media officer at the FDA is quoted as saying, “We don’t have [Actovegin] on our books.” She further explained: “It would have to go through an FDA approval process, and I don’t have any record of that product.” Amina Khan, “What, Exactly Is Actovegin?,” L.A. Times, Dec. 15, 2009.<sup>10</sup> This is not entirely accurate, because there are completed clinical trials of Actovegin on record with the FDA, indicating that the company is possibly planning on making an application of approval.<sup>11</sup> There certainly is something “on record” about it.

However, millions of dollars have to be spent in order to complete an NDA. The Prescription Drug User Fee can itself be over a million dollars.<sup>12</sup> Since any patent on the product must have expired by now, this complicates the picture for any company seeking to invest in getting FDA approval, because they are always at risk of being undercut by competitors who market it as a generic product if the opening of the U.S. market makes this

<sup>10</sup> [http://latimesblogs.latimes.com/booster\\_shots/2009/12/what-actovegin-anthony-galea-tiger-woods.html](http://latimesblogs.latimes.com/booster_shots/2009/12/what-actovegin-anthony-galea-tiger-woods.html)

<sup>11</sup> <http://clinicaltrials.gov/ct2/show/NCT00483730> “Actovegin® Versus Placebo in Patients With Diabetic Polyneuropathy”

<sup>12</sup> <sup>3</sup> <http://www.fda.gov/OHRMS/DOCKETS/98fr/07-5052.pdf> "Prescription Drug User Fee Rates for Fiscal Year 2008"

profitable. However, demand must be strong because Nycomed reports growth in sales and is expanding its manufacturing capabilities.<sup>13</sup>

Browsing the Web makes it clear that the arrest of Dr. Galea spurred a great deal of interest in Actovegin. The drug had previously surfaced as a matter of interest to doping agencies in 2000, when it was temporarily put on the banned list of drugs by the IOC, pending investigation into its use by cyclists.<sup>14</sup> However in two months time it was removed from the list after research was done and it was found not to enhance performance. According to the latest 2011 WADA prohibited list, Actovegin is not prohibited in any sports. It has a proven record of speeding up the healing of muscle injuries. Lee P, Rattenberry A, Connelly S, Nokes L. “Our experience on Actovegin, is it cutting edge?” Int J Sports Med. 2011 Apr;32(4):237-41 (“players in the Actovegin treatment group were able to return to play 8 days earlier”).<sup>15</sup>

Dr. Galea has pled guilty to “misbranding” regarding the labels on Actovegin. The original charges revolved around the misbranding issue as well. Yet it seems appropriate to point out that he believes – as do the authorities in many other countries – that it is a safe and effective medicine. Even though he was not specifically charged with having broken the law by using the medicine here, it seems equally appropriate to point out that he did not

<sup>13</sup> <sup>4</sup> “Sales from our Specialty and Respiratory products also continue to fuel our performance with double-digit growth rates, particularly from Actovegin, Calcichew, TachoSil, Instanyl and Alvesco.” “. . . Actovegin®, [sales of which] which increased by 33.1% . . .” (2010 Fourth Quarter and Annual Report). See also: <http://www.thepharmaletter.com/file/103987/nycomed-may-invest-35-million-euros-in-ukrainian-production-capacities.html>

<sup>14</sup> The first *WebMD* article on Actovegin appeared after, and commenting on, Dr. Galea’s arrest. <http://www.webmd.com/fitness-exercise/news/20091216/faq-on-actovegin>. Other articles proceed from observations about Dr. Galea, such as “world renowned physician who treated Tiger Woods,” noting that Actovegin has been in use for decades. <http://www.nopaindirect.com/actovegin-ergogenic-aid-or-not.html>. Actovegin even has its own Face book page, it seems, referring to Dr. Galea’s arrest, and mistakenly reporting the he was charged with distributing “performance enhancing drugs.”

<sup>15</sup> <http://www.ncbi.nlm.nih.gov/pubmed/21271496>. The article also notes that, despite hopes of athletes at one time, “it is unlikely for this deproteinised substance to have oxygen-enhancing capacity” which would truly make it suitable for “performance enhancement.” See also, Pfister A, Koller W, Treatment of fresh muscle injury, Sportverletz Sportschaden. 1990 Mar;4(1):41-4.

realize that it was not approved for any use, having seen it, from time to time, on web sites advertising “FDA Approved” medicine.

Therefore we do not see how the government can seriously say that qualifying his conduct this way “goes too far,” since it certainly is not an attempt to excuse or even mitigate the misbranding charge to which he has pled guilty.

The table below, in a very simplistic way, illustrates the differences between conventional therapies for muscle and joint injuries and the type of treatments used by Dr. Galea, and a rapidly growing number of physicians in sports medicine and other medical fields concerned with such ailments, like rheumatology.

<b>Injury</b>	<b>Conventional Treatment</b>	<b>Minimally Invasive Alternative</b>
Arthritis-joint inflammation	Cortisone, anti-inflammatories, surgery	Intra articular GH, PRP, PPP, Stem Cells
Muscle Tears	Cortisone	PRP, Actovegin, Traumeel, Zeel
Ligament tears (nonsurgical)	Physiotherapy, time off	PRP, Stem Cells, Physiotherapy, activity modification

It must be born in mind, however, that in each of these therapies there exists a wide number of factors affecting the choices in how to perform them, resulting in substantial differences in the way individual physicians use them, based on their own research and experience.<sup>16</sup>

Thus, when we say that a large number of physicians are adopting these procedures, it should be clear that this field is very complex in application, so one physician’s “PRP” therapy might be actually doing something very different from what Dr. Galea is doing. Unfortunately, his informed voice in this critical developing area of medicine has been all but silenced as a result of this prosecution. This is unfortunate, because there are very few physicians, if any, who are looking at as broad a combination of factors related to these procedures as Dr. Galea.

<sup>16</sup> The reference to “PPP” in the chart above is to “platelet poor plasma.” This is made by a centrifuge to yield platelet levels only about 2 to 2.5 times above the baseline. PPP is used for the tendon-bone interface create a “biological dressing” over the tendon at the bone.

## **Dr. Galea's Research**

Dr. Galea knew from his research that there existed a damaging set of enzymes known as the Protease enzymes (specifically 8, 9 and 13) which, in high concentration, inhibit the function of normal tenocytes within the tendons to lay down healthy collagen, resulting in chronic tendonosis. He began researching how to inhibit these enzymes. He started a research project with Dr. May Jacobson at the Center for Blood Research at Harvard University which would focus on the level of these protease enzymes in the chronically injured tendons. [The study protocol is attached, Ex. D] Unfortunately, his work on this project was necessarily suspended as a result of the instant prosecution

Dr. Galea is also breaking ground in researching how oxygen concentration in the blood may affect the effectiveness of PRP and stem cells in the repair of tissue and prevention of inflammation. Dr. Galea's clinic has two hyperbaric chambers that he utilizes in treatment with PRP, stem cells and various growth factors in regenerative medicine.

## **Dr. Galea's Patients – Who are they?**

Dr. Galea has had patients in track and field and alpine skiing from around the world since the early 1990s.

Dr. Galea was appointed the Head Physician for the Toronto Argonauts Football Club in 2004, a position which he held until 2009, when team ownership changed.

Moreover, he has been the sports medicine consultant for many professional athletes in the NFL, NHL and MLB. He has treated numerous elite amateur athletes and Olympians from Canada and the U.S. and top professionals in sports such as Tennis and Golf. A significant patient was the wife of the owner of an NFL team who was referred after foot injury. She had consulted all of the top surgeons in the US and they could not fix the problem. One of the players told her about Dr. Galea, and she saw him in his Toronto clinic and was treated successfully.

However, it would be a complete mistake to believe that Dr. Galea limits his practice to elite amateur and professional athletes. Approximately 85% of his patients are either

recreational athletes or not athletes at all, but ordinary persons in need of a cure for muscle and joint injuries which had been unsuccessfully treated by conventional treatments.

## **Treatment of US Professional Athletes**

When Dr. Galea became the head team physician for the Toronto Argonaut's in 2004, a lot of the team's players were Americans who had NFL agents. As a result, word started to spread very quickly throughout the NFL that Dr. Galea was able to heal difficult injuries no one else could treat successfully.

In 2006 Dr. Galea received a call from the agent of Jamal Lewis, who in his three-year career at the University of Tennessee, rose to third on the list of all-time rushers. In 1998, Jamal suffered a torn lateral collateral ligament in his right knee and missed the rest of the season. Lewis had been acquired by the Baltimore Ravens as the fifth overall pick in the 2000 NFL draft. The Ravens won the Super Bowl in 2001, and Lewis was only the second rookie ever to rush for more than 100 yards in a Super Bowl. He was also the youngest player to score a touchdown in a Super Bowl.

Jamal's agent told Dr. Galea that Jamal had a knee injury no one could fix and requested that Dr. Galea do a special consultation. They requested that the patient be seen in the United States because Jamal was not likely to be allowed to travel to Canada due to a criminal conviction in 2004. This was a severe case of patella tendinitis. He did see Jamal Lewis under the supervision of a team doctor?

### **Admission as business visitor**

At this time, in 2006, the records of secondary inspection confirm that Dr. Galea alerted border inspectors to the fact that he was going to see Jamal Lewis in Baltimore.

There is some confusion in the PSR, in ¶¶ 22-23, 44-45, about the sequence and context for some of the events that relate to DHS – border crossings and Dr. Galea's efforts to obtain an appropriate visa for a person of his professional standing. As noted in ¶45 he

initially only planned on treating one patient, disclosed his purposes, and under advice of border officials at that time, who admitted him as a business visitor,<sup>17</sup> understood that he could act as a “consultant”, and receive a stipend of up to \$3500 for his services, without raising issues of having to file a U.S. tax return or get approval for working in the U.S. Whether that understanding is accurate or not is not at issue. His original intent was to act merely as a “consultant” in conjunction with the patient’s own doctor – something permitted in every state jurisdiction that is affected. As things took their course he acquired more patients – almost always first seeing them in his clinic in Toronto. But the idea of coordinating with the patient’s home physician, on those often emergent occasions when it became necessary to see the patients in the U.S., quickly fell victim to the exigencies of a hurried schedule.

Dr. Galea set his billing for these US patients to a flat fee of \$3500 in accordance his understanding from the border inspectors. This same fee was applied whether the treatment involved an injection, ultrasound, an IV or just an assessment. The normal cost of PRP therapy would range from \$1500-- \$2500 if the PRP were done in the US – today. In 2007 there was no one else doing this for athletes. In Toronto there would only be a fee of \$750, plus an assessment fee, which might be around \$500. But the \$3500 fee barely covered the cost in lost billings at the clinic for the times that Dr. Galea had to travel to the U.S. to see patients.

Dr. Galea had consulted Canadian counsel on the question of his ability to treat patients in the U.S., and learned that this is permissible if done under the supervision of a physician licensed in the individual state. But he found that this was difficult to apply in practice because of his hectic schedule, the unpredictability of when the patients would not be able to come to Toronto, the growing number of patients, and the patient’s need, in some cases, to keep information about their injuries away team physicians (and therefore team owners) when an injury might not be known but would affect contract negotiations if it were

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<sup>17</sup> The government states that “The defense states that Dr. Galea was given advice by “border officials” that he could enter the United States as a business visitor.” [That is not what we said. He was admitted as a business visitor on the occasions we can tell about. “Border officials” is the way we refer to inspectors who might be from ICE or CBP.

known – especially injuries of the type Dr. Galea was often called in on – ones usually considered untreatable or “career-ending.”

## **Seeing more athletes in the U.S.**

Agents for professional players began calling Dr. Galea to assess and treat the athletes’ injury without disclosing the problem to the team, out of concern that the injury might affect the player’s status or contract negotiations, especially in difficult cases where the customary treatments did not have a history of complete success. This always began with consultation and treatment in Toronto.

In the 2007-‘08, NFL season Dr. Galea started treating more NFL players. All of these players were seen by Dr. Galea in Toronto at his clinic. In some cases, however, Dr. Galea also had to travel to the U.S. to see some of these NFL players, due to their inability to travel for various reasons.

Dr. Galea also successful treatment, in Toronto, of the wife of the NFL owner also contributed to the reputation that was growing in the NFL concerning his skill in treatment. In total, he would treat about 15players in the U.S. In several instances he saved the careers of players or enabled them to achieve milestones – such as Superbowl success – which was otherwise unattainable. But his devotion to these patients had its price, in time away from family, and from his clinic, and anxiety over the inability to set up these visits properly as “consultations” with the supervision of local doctors.

As these referrals in the U.S. grew, it was becoming a huge problem for Dr. Galea. The fees he was getting for U.S. travel were not making up for the lost time at his clinic, and the travel to various locations was exhausting, and he knew that there had to be a more clearly established basis for his activities in the U.S. to come into compliance with whatever regulations applied from and immigration, tax and licensing perspective

Ultimately he sought help in putting this activity on a proper course which would have brought an end to the exhausting and inefficient schedule and the anxiety he was experiencing. An NFL team introduced Dr. Galea to Dr. Theodore Schlegel at the

**Steadman Hawkins Clinic** in Denver in early 2008. The Steadman Hawkins clinics are nationally known for excellence and the advancement of clinical practice and research in joint and tissue injuries. Dr. Galea flew down to meet Dr. Schlegel and started discussing the procedural requirements for him to work there.

Though one of the leading sports medicine clinics in the U.S., the Steadman Clinic had no one doing PRP at the time. They offered Dr. Galea a position to direct a new PRP lab at the facility. The process of filing for a medical license with the State of Colorado was initiated by and went on for months. There were requests by the State of Colorado for more and more information during this application process and time went on.

Mary Anne Catalano was handling this process with Dr. Schlegel's assistant at the time, but very little progress was made. In the meantime, Dr. Galea felt powerless to stop treating these athletes who clearly needed his assistance and who kept begging him to see them in the U.S. where they were unable to come to Toronto.

By the Spring of 2009, the licensing application was still pending. At that point Dr. Galea had still not realized that he needed a Visa to work in the U.S. as well. When this came to his attention he retained the firm of Green and Spiegel in Toronto, a firm with some of the leading immigration practitioners in Canada. They started the process for an O-1A Visa available to individuals in sciences with extraordinary ability, and for which Dr. Galea would most definitely qualify.<sup>18</sup> Catalano took over this process with the lawyers as well and Dr. Galea understood that it was being handled. Shortly before Catalano was arrested, Dr. Galea discovered that hardly anything had actually been done in terms of filing for this Visa. He then took over the process and assembled all of the necessary supporting

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<sup>18</sup> The O-1A visa is for individuals with an extraordinary ability in the sciences, education, business, or athletics (not including the arts, motion pictures or television industry).

"To qualify for an O-1 visa, the beneficiary must demonstrate extraordinary ability by sustained national or international acclaim and must be coming temporarily to the United States to continue work in the area of extraordinary ability."

Extraordinary ability in the fields of science, education, business or athletics means a level of expertise indicating that the person is one of the small percentage who has risen to the very top of the field of endeavor."

Source: CIS Web site description of O-1 Visa

documents. However, by the time that everything was ready to file, Catalano was arrested and it became pointless to proceed with the O-1 application.

*Misstatements were not made on every entry*

A point to be made here is that this course of events did not begin with a plan to use any deception in entering the U.S. Although that is not an element of the offense on which the court will impose sentence, it is in the fabric of the events. In our objections to the PSR we meant only to point out that the occasions for Dr. Galea failing to fully disclose, or misleadingly disclose his purpose for entering the US *as stated in the complaint and the plea agreement* were at the local border crossings. The government was right to correct defense counsel if we gave the impression that we were claiming that Dr. Galea made no misrepresentations at any other time. Surely he did, and he has conceded this, and it was more than the two entries for which there is such a record, on February 20, and September 10, 2009. However we think it is fair to point out that it was not all the time and that especially at the outset, he tried to make clear what he was doing. We do not raise this as “a defense” – as the government characterizes it [Dkt#24 p.9] – because it is not even the instant offense. But it is something in mitigation.

And we do not see how this “ignores Dr. Galea’s admission that he had an agreement with his assistant” as to how to handle border entries on those occasions where she drove across, as the government has suggested. *Id.* That is established, but it has nothing to do with this point, about Dr. Galea’s initial intentions, and his own interaction at the border.

The government tries to trivialize the significance of these initial entries because they occurred “prior to the period covered by the charges in this case.” [Dkt#24 p.10] This, of course, makes no sense. This is what the government, in other cases, calls “background.” We certainly are not suggesting that this history “indicate[s] U.S. government approval for Dr. Galea to practice medicine on patients in the United States.” *Id.* P. 11. All we are pointing out is that the way things developed, was not the way it was intended or foreseen at the beginning.

The PSR does not say, “It was more a question of logistics or convenience as opposed to any real clandestine effort” at these times.

*His medicines were examined and admitted on numerous occasions*

Labels aside, Dr. Galea did not believe that there was anything wrong with bringing in the medicines involved in this case. The secondary inspection records do corroborate what Dr. Galea stated in the probation interview – “Very often when I traveled, the authorities inspected my medical bag before being allowed into the United States.” On many occasions he was cleared by border officials with all the same contents that he usually had in his bag. The government tries to trivialize this by saying “a Customs officer conducting such an inspection would not necessarily examine every article, nor would the officer necessarily recognize if a substance was not approved by the FDA.” *Id.* p. 11. Maybe so, but these were not mere TSA inspections. And there were a lot of them. The government does not suggest how Dr. Galea was supposed to know that the ICE or CBP inspectors were not fully capable of determining what medicines could be brought across the border. He was never cautioned about the medicines. Thus he has a reasonable explanation for his failure to understand that any of the medicines he used, in and of themselves, were not properly brought into the U.S. Of course he fully understands that he had the primary duty to determine that the medicines he brought to the US were acceptable, and he failed in that duty.

## **Practicing without a license**

Even though it is not a federal question, and even though Dr. Galea has not been charged anywhere with any breach of state rules or statutes, the “wallpaper” in this case has been the issue of “practicing without a license.” Of course we do not trivialize the state licensure rules. They are important. However, one only needs to pause a minute to appreciate that the issue is not quite so simple or clear or consequential as it appears at first blush.

Especially in the area of amateur, school and professional sports, the practice of medicine by physicians for individual athletes and teams outside the jurisdiction in which they are licensed is an everyday occurrence. We have made specific inquiries to every jurisdiction implicated in this case. We have been unable to find a single instance of professional discipline or prosecution of a physician for treating a preexisting patient, athlete or not, or a member of the team for which he is a doctor, in a state where he or she is not

licensed. No state has written rules on this question, which indicates that it is regarded as a grey area where a specific directive might not be regarded as useful as allowing any instances to be dealt with through the exercise of discretion.

Indeed, after all the publicity surrounding this case and Dr. Galea's treatments in the U.S., only one state, Florida, actually instigated any investigation, and that investigation concluded with "Letter of Guidance" to Dr. Galea "in lieu of disciplinary action," on September 8, 2011. Florida also has an exception in its statute for team physicians. Of course Dr. Galea takes this investigation and this guidance extremely seriously. However, based on the Florida response, and our investigation, I believe that, were the matter pursued in any other state we could reasonably expect a similar response.

For example, in counsel's personal conversation with the Chief of Licensing for the California Medical Board I was informed that team physicians not licensed in California may come in the state for up to 10 days and treat athletes.<sup>19</sup> Moreover, though there was no recollection of an instance of an athlete's *personal* physician receiving an "Administrative Citation" for practicing without a license, there is typically a fine only for a physician who practices there without a license, up to \$2500, 16 Cal Code Regulations, Div 13, unless there is some seriously aggravating factor involved, such as improper treatment resulting in injury. Similarly, our direct contact with the District of Columbia Board of Medicine indicates that a situation of this type might result in the issuance of a "Letter of Concern" to the physician, a non-public caution.<sup>20</sup>

Of course we do not disagree with the government on this point: there are good reasons for licensing requirements and Dr. Galea fully regrets the choice he made, even though it was for the sake of continuing treatment for his patients. But the question we raise is whether the "practice without a license" backdrop to this case is fairly an "aggravating factor" in the instant misbranding charge, under all the circumstances. The government is correct that the true relevance of it is that the actual practice of medicine – not in consultation with or under the supervision of a locally licensed physician – could be a ground for refusing

<sup>19</sup> See Cal. Business & Professions L. §2076, 2076.5

<sup>20</sup> See, <http://hpla.doh.dc.gov/hpla/cwp/view,a,1195,q,501910.asp>

to admit Dr. Galea to the U.S., and therefore provide a reason for him to conceal his purpose for seeking admission. But the wrongfulness of it *in se* should be measured in light of how it would be treated by an individual state's licensing body. We point out, and the government disregards, that despite the availability of a criminal prosecution in most states, this conduct would likely result in nothing more than an administrative, perhaps not even disciplinary, sanction. That would have much more relevance to a §1001 violation, but we feel it is also pertinent to the instant offense.

Of course this is no excuse or justification for the defendant's actions. He knows this and has admitted it. And it is not offered as such. But the fact that every weekend there are sports medicine doctors attending sporting events outside their home state of licensure to provide medical treatment to their athlete patients or teams with not a single discernable instance of any being disciplined – at least in the states relevant to this case, except for the letter of warning from Florida in the highly publicized case of the treatment of Tiger Woods – surely lessens the significance of this issue when it comes to determining the sentence on the indirectly related charge of misbranding.

## **Spectrum of Treatments on Professional Athletes**

The injuries that Dr. Galea was treating were injuries to tendons, ligaments, and muscle tears, and Osteochondral lesions of the knee, meaning discrete areas of cartilage loss

### *Treatments for Injury to Tendons and Ligaments:*

#### **PRP**

Mainly used for tendon and ligaments, muscle tears, and occasionally intra-articularly. In addition for muscle tears he would use the Actovegin/Traumeel cocktail, especially if they were associated with fibrosis and scarring. These are injected directly into the affected area.

### **Pre-game IV**

The pre-game IV dealt with some anti-inflammatory effects but also addressed making sure they would not re-tear or re-injure a site. It would include normal saline, magnesium, calcium, ATP. The electrolytes would be at a specific dose to help the flexibility of the muscle.

### **Post-game IV**

Most of these athletes sustained inflammatory injuries and as a result, anti-inflammatory IVs were used. In this case he would use a "Post game IV" (anti-inflammatory IV) focused on minimizing the inflammatory reaction around the sites of injury. Including normal saline, calcium, magnesium, B complex, B6 , B5, Vitamin C, Traumeel, Zeel glutathione and in a few more difficult cases Actovegin

### **ATP**

He would also use ATP as an energy source pre-game IV, as a fuel source for the injured muscle or ligament. This would prevent the damaged muscles from becoming fatigued during the game and susceptible to a tear again.

### *Injections Used Around the Knee*

### **PRP**

Injections around the knee most often consisted of platelet rich plasma, injected at precise locations of injury.

### **Actovegin**

Actovegin was sometimes included in what would then be identified as a Homeopathic Injection. The Actovegin formulation was used in 2 ways: (1) as part of a cocktail for muscle tears associated with fibrosis and scarring, and (2) in an IV as an energy substrate for tissue healing.

### **Synphysc or Ostenil**

A hyaluronidase lubricant to act as a buffer in the knee.

### **Regeneration Injection - w/o HGH**

Technically a homeopathic anti-inflammatory cocktail. The Homeopathic anti-inflammatory cocktail was used for generalized chondral wear of the knee, including Osteoarthritis and Chondromalacia, and consisted of Traumeel and Zeel.

### **Regeneration Injection - w/ HGH**

HGH cocktail - identified also as a "Regeneration Injection." This follows Dr. Dunn's protocol in the US, identified in his legal patents filed in Europe and the U.S.. It was used on few of the patients seen in the US. The amount of HGH was minimal, not introduced into the bloodstream, and to assist in the healing of tissue or inflammation only.

The HGH cocktail was only used in 2 types of instances:

1. In an osteochondral lesion as a temporary resolution for the inflammation around the lesion. The only other alternative to HGH was cortisone for this inflammation, which is effective in dealing with the symptoms, but is destructive for the rest of the cartilage. It was Dr. Galea's opinion, and findings, in such instances that the best short-term treatment option was the HGH cocktail. This treatment would buy time for the athlete without cortisone until the lesion could be fixed permanently through surgery.

2. The second application for HGH was in two players who had surgery and developed MRSA (methicillin resistant staphylococcus aureus) infection of this bacterial infection after surgery. This causes significant destruction and inflammation. It was Dr. Galea's opinion and observation that the safest and most effective way to control the inflammation, after the infection is cleared, is the HGH cocktail injection into the knee. The athletes that he treated with this are not playing anymore and were treated mostly in Canada, and only once in the U.S. These injuries were so severe that they ultimately ended their careers and their knees ultimately would need knee replacements in each case.

## **Treatment of Fat Pad Impingement - Cortisone**

### *Fat Pad Impingements*

The “fat pad” lies under the patellar tendon, also known as “Hoffa’s pad” can get inflamed and adhere (stick) to the tendon causing pain. Although cortisone has serious negative effects on cartilage, it has a useful side effect called “tissue atrophy”: it has a tendency to shrink fat tissue. In some cases the fat tissue can get caught in or pinched between the knee cap, inflammation and pain. These players would play with this pain and with extreme difficulty. In these cases the fat tissue has become thickened and scarred. Dr. Galea would use 3-D ultrasound to see where the fat pad is being impinged and inject Cortisone into the thickened tissue so it would recede and not impinge the knee cap.

This is the only case where he would use Cortisone other than for some inflamed bursal conditions. Other doctors would use it far more generously in a variety of conditions. The same is true with commonly used Marcaine anesthetic because of its toxic effects on muscle cells and cartilage cells.

## **Collateral consequences of the investigation, arrest, prosecution, plea and conviction**

Counsel suggest that the Court has to consider the immediate collateral consequences of the investigation, arrest, prosecution, plea and conviction of Dr. Galea. The primary engine of damage was the merciless and deliberately false media accounts which described the case as a “doping” case and as involving “performance enhancement drugs.” There was nothing in the charges or anything the government ever said to cause this, and the government has completely dispelled any hint of it now. However, these malicious accusations and innuendo could have put a *complete end* to the career of a physician who did not enjoy such an excellent reputation as a medical doctor and person. Of course there are many consequences which flow directly from the plea and conviction.

- Upon his arrest Dr. Galea was asked to resign from every organization board he had volunteered to serve on, a cogent symbol of public disgrace.
- The Canadian Academy of Sports Physicians, his primary sports medicine association, summarily removed him because of all the Media allegations. (A hearing has been scheduled to review that action)
- Memos were circulated by professional sports associations, including the NHL, NBA, MLB instructing players not to seek his medical attention.
- A memo was issued at York University that any athlete from their program to see Dr. Galea would be kicked off their teams.
- Dr. Galea was turned down by some insurance carriers because of the adverse media coverage.
- Dr. Galea had been chosen to act as the Moderator of the North American Symposium on PRP Therapy, a very prestigious event in his field. The brochure is attached, along with the humiliating Daily News articles publishing criticism about his selection and also his eventual removal from that position. Attached as Ex. E
- Dr. Galea has been tirelessly and publicly ridiculed for 2 years as being involved in “performance enhancement” by a mindless and avaricious press, which is not only false, but anathema to his professional beliefs and values.
- Dr. Galea’s teaching privileges at the University of Toronto Dept. of Family Medicine were suspended.
- Defending this case, and in the adverse impact on his practice has involved a huge financial burden that will impact on him and his family for years to come.
- There has been a huge stress on Dr. Galea’s family. His children have been teased that their father was going to jail and that he was involved in drug smuggling.
- This conviction may well render him inadmissible to the United States resulting in at least very costly – in the largest sense – delays in his ability to seek or obtain a possible waiver of inadmissibility. Of course this has immediate and devastating

impact on his potential for a research, teaching, or medical position in the U.S. with a sports team or a sports medicine clinic, like the Steadman Hawkins clinic in Denver.

- The arrest and prosecution has damaged Dr. Galea's Harvard academic research relationship. He started a research project with Dr. May Jacobson at the Center for Blood Research at Harvard University relating to the subject of "Cytokine and Chemokine Release from Platelet-rich Plasma." His participation in this funded research was suspended because of his arrest.
- He has already paid the substantial \$275,000 forfeiture provided for in the plea agreement, which absolutely constitutes criminal "punishment" in connection with his conviction.
- Last but not least, Dr. Galea's Canadian medical license will be reviewed by the College of Physicians and Surgeons of Ontario as a result of his conviction.

## Mitigating Factors

All of the above information establishes mitigating factors in this case which ought to be taken into account in sentencing.

### **Dr. Galea's professional achievements, humanitarian activities, level of care**

As just mentioned above, Dr. Galea's extraordinary medical achievements and the generosity that is apparent from the testimonials provided, ought to be considered a mitigating factor

### **Dr. Galea brought in medicine not "drugs"**

The fact is that the misbranding at issue in the plea – and the other substance related conduct in the original charges - had to do with *homeopathic medicines*, solely for the purpose of healing injuries. The safety of these medicines for use in accepted, validated and

even outstanding medical treatment, are not subject to question. This is surely a mitigating factor.

### **The “deception” involved in the misbranding was slight**

Even if the bottles imported were in part in a foreign language, for the most part the identity of the substances – the brand name – was evident and in English.

### **The medicines were repeatedly allowed in**

When one considers that Dr. Galea was undoubtedly screened at the border many times, his medical bag and its contents were examined, and the border inspectors always allowed these medicines in, it is not fair to impute to Dr. Galea knowledge – as originally charged – that the medicines were not permissible.

### **The widespread and notorious use of nutropin in the U.S.**

It certainly is a mitigating factor that there was such widespread “off-label” use of HGH in the United States. The most prominent Web site, that of Dr. Dunn, the real pioneer in some sense of the treatment using HGH, firmly declares that “off-label” use was permitted. To the extent that the use at all of HGH in treatments in the U.S. is to be considered, it must be considered in the context of a confusing regulatory environment where there was open and notorious use of HGH for treatments like Dr. Galea from which he would have been unable to deduce that his treatment was improper.

### **Dr. Galea’s attempts, though imperfect, to comply with rules and obtain a special visa**

Though the effort was not exhaustive, and more should have been done surely, Dr. Galea did make some efforts toward getting a visa to cover his high professional skills, and he did seek out legal advice about how he could provide medical services in the U.S. Clearly, he let his compulsion to treat his patients obscure the legal requirements, and he has paid and is paying huge price for this. But his intentions were not anti-governmental or evil in any way.

## **Foregoing extradition**

Dr. Galea volunteered to surrender to the jurisdiction of the United States and obviate the need for the commencement of extradition proceedings. This was with no promise by the government as to what it would agree to. The Court needs to appreciate the degree of courage that it takes for such an individual, with virtually everything they have struggled to achieve, and care about, as well as their liberty and the welfare of their family at risk, to surrender to a foreign government, where there had been such unrestrained hostile and false public accounts completely distorting the matter. On top of this, Dr. Galea was aware that if he reached an agreement with the government involving the entry of a guilty plea to any offense, there would be no way to know in advance that, despite his clean record, his good intentions, and the lack of adverse consequences to his conduct, he would not be imprisoned, or even imprisoned for many years. This would be almost unheard of in Canada where it is accepted that the “finality” achieved by an agreed resolution of a criminal case includes the ability of the accused to know what type of sentence he would be getting. Of course that would most often be the case in New York state courts.

All of these factors are mitigating factors which ought to be considered.

## **Non-Guidelines sentence**

The draft PSR stated that “As of the date of dictation, the defendant has not provided the specific reasons for a request outside of the advisory guideline range.” Following our comments on the PSR, the probation officer included the following summary of the grounds we brought forth:

These factors include but are not limited to the following: the defendant’s professional achievements, humanitarian activities and level of care; the position that he brought medicine into the United States, not “drugs”; the “deception” involved in the misbranding of the medicine was slight; the defendant’s attempts, though imperfect, to comply with rules to obtain a visa; the fact that he voluntarily

came to the United States to address this issue rather than extradition proceedings.

The existing guideline range would be the same as for an unscrupulous “trainer” bringing in substances to be distributed in dangerous dosages for adolescent athletes for purposes of performance enhancement. Insofar as HGH the statute – and any misbranding associated with HGH importation – was specifically adopted with “performance enhancement” abuse in mind.

Here we have a physician, providing top-level medical care, to established patients at his clinic in Canada. Only for the convenience of his patients or necessity, did he come to the U.S. to provide treatment.

However, in juxtaposition to his high professional and personal achievements, and the great things he has done medically and personally for others, as a direct consequence of his arrest and prosecution he has suffered enormously. His conviction alone is a serious threat to his career, not only in terms of censure, but the possibility of being readmitted to the United States to carry on research, join clinics, train U.S. doctors, and achieve the highest level he could attain in his profession.

All this is a way of saying that the guideline range here which assumes incarceration is clearly way beyond what might be necessary to achieve the legitimate purposes of sentencing in this case, where, by any reasonable assessment, a non-incarceration sentence, except “time served,” must be the presumptive sentence. This is not a case of a type envisioned by the USSG, and there is absolutely no “general deterrence” to be considered in such a case because the conduct here only arises because of the unique medical skill and abilities of Anthony Galea, and his singular dedication to the care of his patients at the expense of his own security. There are no other “Dr. Galeas” out there to deter in such a setting. His case is unique.

It also cannot be overlooked that Dr. Galea has agreed to an enormous forfeiture in this case, incurring debt to do so. This will be very substantial punishment to him—it is a *criminal forfeiture* and therefore in the nature of a penalty.

We also add that Dr. Galea did everything asked of him by the government in this case, and spent many hours of his time reviewing the events, explaining the medical complexities of the treatments he used and the medical problems presented by each patient. Yet the government has only moved for a single point reduction under §5K1.1, the other point under §5K1.2, relating to the voluntary surrender without extradition proceedings. The Court can consider whether under all the circumstances the current guideline range is simply an inappropriate starting point for thinking about the sentence in this case.

Thus, a non-guidelines sentence must be presumed, because, given a fair assessment of the seriousness of the conduct and the character of the offender and all the circumstances, a guidelines sentence would shock the conscience and sensibilities of anyone familiar with the true facts in this case.

## **Letters in Support: A Brief Overview**

The three volumes of letters in support of Dr. Anthony Galea consist of 117 contributions from family, health care professionals, patients and friends. In addition to the testimonials included in this submission, the Court should be aware that counsel on behalf of Dr. Galea continues to receive countless unsolicited telephone calls and e-mails offering support and paying tribute to an outstanding physician, a caring, decent and committed human being.

Neither Dr. Galea nor counsel on his behalf take issue with the serious nature of his misconduct nor his clear and unequivocal acceptance of responsibility for the wrongdoing set out in the Plea Agreement. Nevertheless, it is submitted on Dr. Galea's behalf that his exemplary life, his humanitarian efforts, his outstanding contributions to his community, his sincere remorse and contrition and the devastating collateral damage to his reputation and his professional future dictate that the balance struck on the penalty continuum should fall in his favor.

## Family

The thoughtful expressions of support by his wife, children, sister, his former spouse and his long term office manager provide insight into a caring and compassionate man whose strength of character and spirituality are relied upon by the people closest to him. His wife observed: 'we have done our best to help the older children understand what is really happening rather than what has been written and our younger ones to understand that even good people can make mistakes and that it is important to learn from them, grow from them and continue to work to make the world a better place.' His daughter remarked: '"your dad saved my life" is a statement most people will go a lifetime without hearing; for me, it is almost become a daily occurrence...but nothing compares to what he has done for his family.'

## Application for Work Status in the United States

Seven letters have been included which were filed in 2009 in support of Dr. Galea's application to the Department of Homeland Security to obtain a work permit in order to accept the offer of employment which had been extended to him by the prestigious Steadman Hawkins Clinic in Denver, Colorado. Both Dr. Schlegel and Dr. Philippon rank among the most respected sports physicians in the United States of America and both confirm Dr. Galea's excellence and his recognition as an international expert in the field of science and in the top 1-2% of individuals in the world who have focused on the emerging technology in the healing of tendon and ligament injuries. '...Dr. Galea possesses and demonstrates a command of tissue regeneration that is unparalleled in the medical field...[which] have made him one of the world's leaders and most sought-after experts by both physicians, athletes and patients around the globe.' That international reputation is confirmed by tributes from Professor Shlomo Noy and David Weinberg of the Sheba Medical Center at Tel Hashomer, Israel as well as Dr. Naama Constantini of the Hadassah-Hebrew University Medical Centre in Jerusalem.

Included in the material is a letter of support from a patient who observed that he could '...say without hesitation that Dr. Galea was one of the top physicians that I have had the opportunity to consult...he is one of the kindest, compassionate young men that I have

ever had the opportunity to meet. He would not accept a fee from me for his consultation and treatment. The only request he had was a signed copy of my book." This was the support offered by Ambassador Andrew Young, Past President of the National Council of Churches and to all North Americans an historic and inspirational leader.

## **Physicians and Health Care Providers**

The scope and breadth of Dr. Galea's reputation as a healer and health care provider is remarkable. Physicians speak of his '...rare skill of approaching his patients with open eyes and ears...[and] his very original way of thinking imparts to his performance a kind of "magic touch" that arouses the envy of many colleagues. Tony, unlike many physicians, never keeps his ideas and innovations to himself.' His colleagues in health care not only pay tribute to his innovation and dedication but persistently recognize his research skills and his contributions to the advancement of the healing arts. As Dr. David Ablack noted: 'Dr. Galea is on the cutting edge of medical rehabilitation. He is constantly bettering himself to help others and has sacrificed a great deal of his life for this pursuit. As a result, hundreds, if not thousands, of people are injury free and able to excel in their athletic endeavours both in the professional and recreational arena.'

## **Sports Teams Owners/Coaches**

David Cynamon, the former owner of the Toronto Argonauts of the Canadian Football League stated of Dr. Galea that: 'I can honestly say that I have never met a more compassionate, dedicated, intelligent, loyal and authentic individual in all of my life.' He noted that he was '...personally so impressed and humbled by Dr. Galea's efforts [in helping injured soldiers and civilians in Israel] that I commissioned a statute of art that currently sits on the front lawn of the Chaim Sheba Medical Centre...that contains a plaque...in Dr. Galea's honor.'

## **Patients and Friends**

The 88 letters of support found in Volumes 2 and 3 of the materials confirm both the extraordinary success of Dr. Galea's insightful and innovative approaches to sports injuries but of almost equal importance, as the measure of the man, address his commitment to his patients, his unfailing dedication to finding solutions and a doctor-patient relationship which should serve as a model for health care practitioners in both Canada and the United States.

Retired Rear Admiral James J. Carey who served for nine years under President Reagan and President Bush as the Vice Chairman and Chairman of the Federal Maritime Commission and who has received countless decorations, including four awards of the Legion of Merit, is fully aware of the misconduct which has brought Dr. Galea before the Court for sentencing. Nevertheless, Rear Admiral Carey views Dr. Galea as '...a man truly exceptional character...a person through extensive charitable work and giving back to society is almost without equal, a patriot with commitment to his faith and religion and fatherly caring for his seven children...an exceptional human being.'

It would be difficult to summarize or compress the inspirational tribute to Dr. Galea provided by Stacey Sheron, a 35 year old woman from Atlanta, Georgia. 'Dr. Galea never gave up on me. Even when I had given up on myself he kept encouraging me. He told me I had potential, and I was someone special. I was someone worth fighting for. He was bringing me out of the darkness that I feared I would spend the rest of my life in and into the light...now thanks to him, I am living independently...thanks to the compassion of Dr. Galea, I am finally living again. Dr. Galea has taken me from being in a hopeless situation to a young woman with a bright future ahead. He is an absolute miracle worker. Dr. Galea is a total giver and healer.'

Were this an isolated testimonial, Ms. Sheron's comments might be of little assistance in assessing the quality of Dr. Galea's life. Her words resonate with virtually every description of the quality of care, his attention to detail and extraordinary energy which his patients describe as virtually unique in the course of their attempts to deal with their injuries. These patients, some of whom are competitive athletes most of whom are ordinary people, also describe a physician who was never driven by financial motives and who frequently

waived or reduced his professional fees. They speak of a doctor who treated "the whole person" and who was the leader of a dedicated group of health professionals at his clinic who addressed all aspects of injury treatment: physiotherapy, chiropractic and massage therapy. They also describe a crowded waiting room in which some patiently wait for hours to see their Dr. Galea because he is worth the wait. They describe their examination which isn't dictated by the six minute rule reflected in the medical tariff of the Ontario health care system but an examination that takes as long as is required to thoroughly discuss, explain and plan the most appropriate protocol for dealing with the problem. His waiting room, as the letters of reference demonstrate, are filled with people from all walks of life including members of the judiciary, prosecutors, police, customs and correctional officers, pastors professional athletes, recreational athletes, seniors, students and children.

One of Dr. Galea's patients, Rick Marszlek, is representative of the average man/woman treated at his clinic. Mr. Marszlek noted: 'I am not rich and famous by any means. I am a meat cutter working in a retain grocery store...when I visit Dr. Galea's office, I see so many pictures given to him by world renowned athletes. Every one of them has signed the pictures saying...thank-you for saving my career. Thank-you for helping me enjoy life. Thank-you for keeping me going...but what really impresses me are the every day women and men of all ages that I sit next to in the waiting room...I talk to these people or overhear their comments. Everyone only has positive comments and statements of Dr. Galea's ability and knowledge. They say things like "I would never go anywhere else." And they say things like "thank-god I have him treating me." This confidence is obvious with everyone who comes into visit Dr. Galea. I see it on the faces and hear it spoken. And these are just everyday individuals. I am sure there are some wealthy people sitting next to me but they are there for the same reason as I am. To be treated by the best.'

His patients, almost universally, speak of his professionalism, sincerity, generosity of spirit and a trusting relationship which they have developed with Dr. Galea. His thoroughness, his kindness and his devotion to the quality of care are both understood and appreciated by his patients. His patients also demonstrate a knowledge of their injury, an understanding of the available treatments and a recognition, as noted by Lorna Blumen that Dr. Galea gave her and '...so many other patients, a chance to heal and continue to live our lives strongly, professional athlete or not. And it's because of his curiosity, his ability to think

outside the box, to devise new ideas, to adopt ideas from other countries, to use standard treatments in non-standard new ways, that he has been able to help so many people.'

## Afterword

Dr. Galea's professional dedication has always been selfless and has never been self centered. It would never have been his intention to receive accolades, bank them away so that he might some day utilize them as credits against his future transgressions. Nevertheless, a life well led, dedicated to humanitarian interests, to medical research in the betterment of our community can legitimately be called upon to mitigate and to be balanced in arriving at an appropriate penalty which now must be imposed upon Dr. Galea by this Honorable Court. We urge Your Honor to recognize the extraordinary good character of Dr. Galea in mitigation of the guideline. Chief Justice Earl Warren observed that 'it is the spirit and not the form of law that keeps justice alive.' It is our respectful submission that the spirit of justice should, in the unique circumstances of this case, result in a non-custodial sentence.

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Brian H. Greenspan, Barrister  
GREENSPAN HUMPHREY LAVINE  
15 Bedford Road  
Toronto, Ontario, Canada M5R 2J7  
Ph: 416-868-1755  
Facs: 416-868-1990  
[bhg@15bedford.com](mailto:bhg@15bedford.com)

Respectfully submitted,  
/s/ Mark J. Mahoney

Mark J. Mahoney, Esq.  
HARRINGTON & MAHONEY  
70 Niagara Street, 3<sup>rd</sup> Floor  
Buffalo, NY 14202-3407  
Ph: 716-853-3700  
Facs: 716-853-3710  
[mmahoney@harringtonmahoney.com](mailto:mmahoney@harringtonmahoney.com)

*(Attorneys for Anthony Galea )*